

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

ERIC L. JEFFRIES,	:	
	:	Case No. C-1-02-351
Plaintiff,	:	
	:	(Judge Beckwith)
vs.	:	(Magistrate Judge Hogan)
	:	
CENTRE LIFE INSURANCE COMPANY,	:	<u>DEFENDANTS' AMENDED</u>
et al.,	:	<u>DAUBERT MOTION AND</u>
	:	<u>MEMORANDUM IN SUPPORT</u>
Defendants.	:	<u>REGARDING HEPATITIS B</u>
	:	<u>VACCINATION CAUSATION</u>

Now comes Defendant Centre Life Insurance Company and moves to exclude the testimony of Dr. Geier, Dr. Waisbren and and Dr. Hyde pursuant to the mandate of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786 (1993). Their testimony is not reliable nor scientifically valid.

Respectfully submitted,

s/Peter M. Burrell

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MEMORANDUM IN SUPPORT

I. INTRODUCTION

At issue in this case is whether Mr. Jeffries' disability is caused by a physical sickness or a mental disorder. After review of the neuropsychological examination and testing of Mr. Jeffries by Dr. Hartings, DMS has determined that Mr. Jeffries has somatization disorder, severe; obsessive-compulsive personality disorder; and cognitive disorder. Pursuant to the terms of Mr. Jeffries' individual disability policy, he is entitled to 24 months of benefits for a disability caused by a mental disorder. Mr. Jeffries has been paid the entirety of the benefits to which he is entitled.

Since the inception of his claim, Mr. Jeffries has resisted psychological evaluation. He did not meet with Dr. Hartings until ordered by the Court. Despite the medical evidence to the contrary, Mr. Jeffries' goal is to establish that his disability is a physical one. To this end, it is anticipated that Plaintiff will offer the testimony and/or reports of some of his consulting physicians that his Hepatitis B vaccination has resulted in an immuno-suppressive disorder. There is no valid scientific basis for this testimony. Any connection between Mr. Jeffries' symptoms and his Hepatitis B vaccination is speculative and not supported by sound, scientific method. Under the mandate of *Daubert v. Merrill Dow Pharmaceuticals*, there is no reasonable fit between the opinion his doctors seek to offer, that he has physical symptoms that were caused by his Hepatitis B vaccination, and any scientific method or theory which would support such a conclusion. As such, testimony on this issue must not be allowed.

II. ARGUMENT

A. Expert Testimony Must Be Relevant, Reliable And Scientifically Valid.

The Daubert gate-keeping requirement requires that the testimony of an expert witness be both relevant and reliable. In addressing the admissibility of proposed expert testimony, the Supreme Court has explained that such testimony must “be supported by appropriate validation -- i.e., ‘good grounds,’ based on what is known” and it must be relevant and helpful to the trier of fact. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590-91, 113 S. Ct. 2786. “Expert testimony which does not relate to any issue in the case is not relevant and, ergo, not helpful.” *See id.* at 591, *citing* 3 Weinstein and Burger, pp. 702-18. The trial judge’s responsibility to admit only expert witness testimony that is both reliable and relevant has been referred to as the “*Daubert* gate-keeping requirement.” As the Supreme Court has recognized:

The objective of that [gate-keeping] requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.

See Kumho Tire Company Limited v. Carmichael, 527 U.S. 137, 119 S. Ct. 1167, 1176 (1999).

Acknowledging that the rules of evidence permit wide latitude for the admissibility of relevant evidence, the United States Supreme Court nonetheless recognized that Rule 702 “clearly contemplates some degree of regulation of the subjects and theories about which an expert may testify.” *See Daubert*, 509 U.S. at 589. An expert may not simply put forth conclusory opinions or restate the arguments of counsel or the claimant under the guise of an expert opinion. As stated by the courts, the word “knowledge” as used in Rule 702 “connotes more than subjective belief or unsupported speculation.” *See id.* at p. 590. The dual requirements of reliability and relevance are appropriate considering the potential, and

sometimes disproportionate, impact of expert testimony on the trier of fact. The Supreme Court has stated:

Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility. That these requirements are embodied in Rule 702 is not surprising. Unlike an ordinary witness, . . . an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation. . . . Presumably, this relaxation of the usual requirement of firsthand knowledge -- a rule which represents a "most pervasive manifestation" of the common law insistence upon "most reliable sources of information" . . . is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline.

See id. at 592 (internal citations omitted). This consideration of a valid scientific connection asks whether there is a "fit" between the inquiry and the theory espoused by the "expert." *Id.* at 591.

This requirement of reliability applies not only to experts offering testimony on scientific matters, as was the issue addressed in *Daubert*, but to all experts who purport to possess "knowledge" helpful to the trier of fact. *See Kumho Tire*, 19 S. Ct. at 1173. It is the duty of the court to evaluate and determine whether the proffered evidence is both relevant and reliable. To be reliable from an evidentiary standpoint, the testimony must be scientifically valid. The Court noted "[i]n a case involving scientific evidence, evidentiary reliability will be based upon scientific validity." *See id.* at 590, n. 9.

When assessing reliability, a court must consider the following factors: (1) Whether the concept has been tested; (2) whether the concept has been subject to peer review; (3) what the known rate of error is; and (4) whether the concept is generally accepted by the community. *See id.* Although the Supreme Court has recognized that not every factor will apply in every case, these are all factors to be considered. *See Kumho Tire*, 119 S. Ct. at 1171.

In this case, Plaintiff seeks to submit opinions regarding causation. He has been diagnosed with somatoform disorder which has manifested itself in his obsession to find a physical ailment. Mr. Jeffries has described physical pain and other maladies which his treating and consulting physicians have documented. His physicians have in general been unable to explain the cause of these problems and objective testing has ruled out all of Mr. Jeffries' possible diagnoses. Dr. Michael Hartings determined during his neuropsychological examination and testing of Mr. Jeffries that he suffers from somatoform disorder. Mr. Jeffries has actual physical symptoms, but these symptoms are caused by a mental disorder.

Mr. Jeffries argues that he does not have somatoform disorder but has some sort of physical disorder which would entitle him to benefits beyond the two-year limitation of his policy. Mr. Jeffries' physicians have been unable to collectively assign a specific diagnosis to his problems. Although a vast array of disorders have been considered, objective testing has ruled out any specific diagnosis. At this point, Mr. Jeffries is primarily arguing he has symptoms of chronic fatigue syndrome. In any event, the question becomes what caused these symptoms. Mr. Jeffries argues that these symptoms began after he received a Hepatitis B inoculation. Mr. Jeffries has obtained the opinions of other consultants who opine that the Hepatitis B inoculation can cause chronic fatigue syndrome and/or myeloencephalitis, which is basically another word for chronic fatigue syndrome. The opinions of these physicians are not supported by sound medical science and serve only to advance their individual research goals.

B. There Is No Scientific Validity For The Theory That Hepatitis B Inoculations Cause Chronic Fatigue Syndrome Or Any Of Mr. Jeffries' Symptoms.

Setting aside the myriad of diagnoses that have been considered and rejected in Mr. Jeffries' case, the diagnoses of chronic fatigue, myeloencephalitis, and immune cerebritis

remain.¹ Drs. Geier, Hyde and Waisbren have offered the opinion that Mr. Jeffries either has CFS or myeloencephalitis (“CFS/ME”) and that his CF/ME was caused by his Hepatitis B inoculation. There is no scientific fit between this opinion and Mr. Jeffries’ factual symptoms. The idea that a Hepatitis B inoculation can cause CFS/ME is speculative and not permitted under *Daubert*.

None of Mr. Jeffries’ consulting physicians have been able to put forth any scientific study that causally link Hepatitis B to CFS/ME. It is acknowledged that there are anecdotal references to adverse effects of Hepatitis B. Despite these anecdotal references, Hepatitis B is a required inoculation for all children born in the United States. The Hepatitis B inoculation is considered safe by the Center for Disease Control. Moreover, Mr. Jeffries’ symptoms are not consistent with symptoms recorded in the anecdotal referenced relied upon by Drs. Geier, Hyde and Waisbren.

Dr. Geier advocated on behalf of Mr. Jeffries for compensation for his alleged adverse reaction to the Hepatitis B vaccination. In support of the application Dr. Geier relied upon statistics from the Vaccine Adverse Event Reporting System (VAERS) database. VAERS is a voluntary forum to which adverse reactions to vaccines can be reported. Dr. Geier’s reliance on VAERS as statistical support for his adverse vaccine reaction conclusions has been criticized.

The American Academy of Pediatrics has recently authored an opinion that reliance on VAERS for evidence of an adverse reaction pattern is unacceptable. *See* Exhibit A. As the AAP has concluded “inherent limits of VAERS include incomplete reporting, lack of verification of diagnoses, and lack of data on people who were immunized and did not report problems.” *See id.* Moreover, VAERS does not contain enough information to determine whether the alleged adverse reaction is actually related to a vaccine or other symptoms present at the time of

¹ Dr. Pretorius’ diagnosis of immune cerebritis is addressed in a separate motion.

inoculation. Dr. Geier's reliance on VAERS has been criticized and has been established not to be sound science. "Data from VAERS are useful for hypothesis generation (raising questions) but should not be used for research aimed at determining whether vaccines cause certain health problems (hypothesis proving), as was done in the article by Geier and Geier." *See id.* at p. 1.

Although Dr. Geier references several studies in his Affidavit in support of Mr. Jeffries, none of these studies scientifically tie Mr. Jeffries' complaints of chronic fatigue to a Hepatitis B vaccination. He relies on VAERS to support his advocacy of Mr. Jeffries but reliance has been criticized by his peers and is not scientifically sound. As such, Dr. Geier's conclusion that Mr. Jeffries' Hepatitis B vaccination caused his disability symptoms must be excluded.

C. Anecdotal Reports Of Adverse Hepatitis B Vaccinations Reactions Do Not Support Mr. Jeffries' Theory.

In consideration of a *Daubert* motion, it is acknowledged that not all of the factors identified by the Supreme Court in the *Kumho Tire* case will necessarily be present in each instance. With regard to the reports of Dr. Hyde and Dr. Waisbren however, none of the factors are satisfied. Even if a flexible approach is taken, it is clear that their methodology is not scientifically supported. Rather, they conclude that because Mr. Jeffries has documented symptoms and because he received a Hepatitis B vaccination, that this vaccination caused his problems. The cover page of Dr. Waisbren's anecdotal reports tellingly sums up his theory. He gives a quote from Ecclesiastes 1.4: "Only that shall happen which has happened. Only that occurs which has occurred. There is nothing new beneath the sun!" Neither Dr. Waisbren nor Dr. Hyde have provided any scientific evidence that would support their theory.

In addressing the *Daubert* focus on not only principles and methodology but also the conclusions that can be generated therefrom, the Supreme Court has stated:

Conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

See General Electric Company v. Joiner, 522 U.S. 136, 146 (1997). To say that Mr. Jeffries' problems were caused by his Hepatitis B vaccination simply because he received the vaccination is too great a leap.

Unlike, Dr. Geier who targets a variety of safe vaccinations as potentially causing physical problems, Dr. Hyde and Waisbren have focused on adverse reactions to Hepatitis B inoculations. Like Dr. Geier, neither Dr. Waisbren nor Dr. Hyde can point to any scientific study or data which would support a causal connection between Hepatitis B vaccinations and CFS/ME or post-vaccinal encephalomyelitis as Dr. Waisbren has diagnosed. Their reliance is exclusively on anecdotal reports from other adults who have claimed an adverse reaction. This is not reliable scientific methodology.

A review of the anecdotal reports is also of interest here. First, Mr. Jeffries received only one Hepatitis B vaccination. The subjects in Dr. Waisbren's anecdotal studies reports had a series of at least two Hepatitis B vaccinations. Mr. Jeffries had a single vaccination, yet claims a more devastating effect.

Second, Mr. Jeffries does not have arthritis. All of the anecdotal reports submitted by Dr. Hyde and Dr. Waisbren verify the presence of frank arthritis in the subjects adversely affected. Mr. Jeffries has had a negative bone scan and clearly does not have arthritis.

Third, Mr. Jeffries' blood tests do not contain the antibody to Hepatitis B. In the other anecdotal reports submitted by Mr. Jeffries' consulting physicians, the individuals in question had been able to verify the presence of antibodies to Hepatitis B. Although Mr. Jeffries claims

an adverse reaction, he does not actually have the Hepatitis B antibody in his system. This is a questionable finding and one completely ignored by his consulting physicians.

Finally, Mr. Jeffries' disabling problems were not contemporaneous with his receipt of the Hepatitis B inoculation. Mr. Jeffries claims that immediately after his Hepatitis B inoculation in June 1997, he had adverse symptoms which he reported to his physician. These symptoms included pain, night sweats, and fever. These symptoms resolved, however and he reported to Dr. Nunlist-Young that he was feeling much better. His report of recovery was interestingly tied to his decision to switch health insurance carriers. It was not until more than a year after Mr. Jeffries' Hepatitis B inoculation he claims he became disabled. Even more interesting is the fact that his disability began after he had increased his insurance coverage.

Not only is Drs. Hyde's and Waisbren's reliance upon anecdotal evidence scientifically misplaced, it is not supported by the facts of Mr. Jeffries' claimed disability. Mr. Jeffries' consulting physicians have been unable to support their theories with scientific evidence. They, therefore, turn to anecdotal support. The facts of Mr. Jeffries' alleged disability are not consistent with the reports of others who have suffered allegedly adverse reactions to Hepatitis B, however. There is no sound scientific or even anecdotal evidence in this case, and as such, the opinions of Drs. Waisbren, Hyde and Geier must be excluded.

III. CONCLUSION

There is not reliable and verifiable scientific evidence that Mr. Jeffries' Hepatitis B vaccination caused his disability. The methodology of Drs. Geier, Hyde and Waisbren is flawed,

and in the cases of Hyde and Waisbren non-existent. Their testimony is circular, unreliable and must be excluded under *Daubert*.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been filed with the Court by electronic means on this 12th day of December 2003. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

s/Peter M. Burrell
Peter M. Burrell, Esq.

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